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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,156	11/19/2001	Anders Bjorling	P01,0261	8752
26574	7590	02/13/2004		
SCHIFF HARDIN, LLP PATENT DEPARTMENT 6600 SEARS TOWER CHICAGO, IL 60606-6473			EXAMINER MACHUGA, JOSEPH S	
			ART UNIT	PAPER NUMBER
			3762	2

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/993,156

Applicant(s)

BJORLING, ANDERS

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

***Drawings***

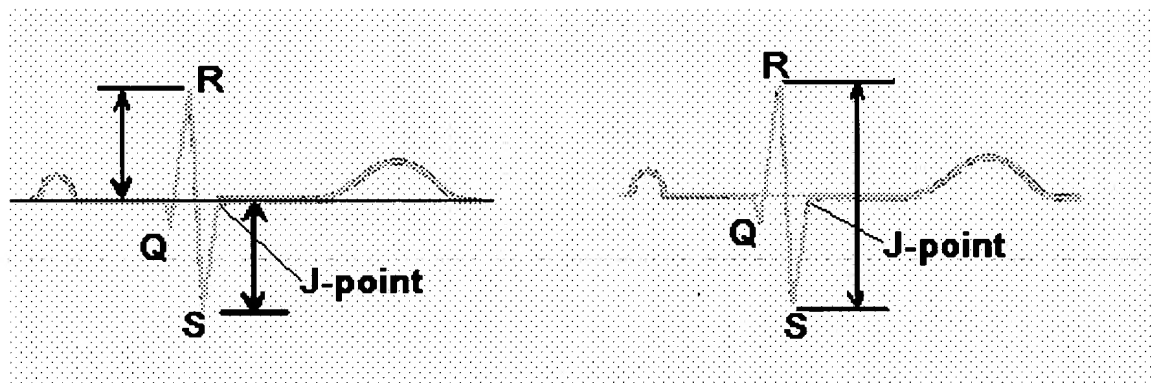
1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference numerals 41-46 noted on page 7 are missing. Also the yes/no in decision block 56 and 105 is missing from Figures 5 and 10; "is separated" in block 63 of Figure 6 should be corrected. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Specification***

***Claim Rejections - 35 USC § 112***

2. Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The exact function of the template having data that is populated by information obtained from the patient wearing the implant is not understood. Also, the specification states that the maximum deflection is recorded. Is the maximum deflection referenced the R-S segment or the maximum deflection above or below the neutral line of the ECG?



3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5, 6, 9, 10, 25, 26, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 9, 25 and 29 are indefinite. The claims fail to include the step of or device for updating the filter with data from the newly created template. Therefore, the step of "filtering the IEGM signal with the matched filter having the template" is not supported.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrugia et al #5542430.

It is considered obvious that after the IECG signal in Farrugia et al device is stored in some manner in the device either with or before the filter. Also, the neural net (column 6 lines 10-29) would categorize, determine and create the template therefore, the particulars of the claims would be provided for.

7. Claims 11, 12, 14-18, 21, 31, 32, 34 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrugia et al #5542430 in view of Sweeney et al #6684100.

Farrugia et al discloses a cardiac signal detector that includes a neural network that categorizes, determines and creates a QRS template. Not disclosed by this reference is identifying one of the classes or categories that most represents an actual QRS complex.

Sweeney et al discloses a cardiac signal detector that includes a template box or zone that best represents each of the known types of heart signals (column 8 Lines 18+.) The reference teaches extracting features based on time width, amplitude, amplitude width, similarity, etc. The reference also teaches creating classes and updating them.

Given the teaching of Sweeney et al it would have been obvious to one of ordinary skill in the art to add an updateable template to Farrugia et al's device having classes and zones that best represent the known heart signals (including a typical ECG signal.) To determine the class having the representative QRS complex based on similarity, minimum dissimilarity, largest amplitude, largest negative amplitude or other common features associated with a normal physiological ranges as recited in claims 11,12 and 14-18 would also have been obvious given this references teaching.

8. Claims 13, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrugia et al #5542430 in view of Sweeney et al #6684100 as applied to claims 11, 12, 14-18, 21, 31, 32, 34 and 36-40 above, and further in view of Errico et al.

9.

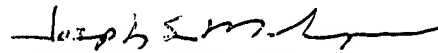
10. Errico et al discloses the use of the commonly known Generalized Lloyd Algorithm to classify pattern data. To use this method in the device of the proposed combination to locate clusters or central points in the data would have been obvious to one of ordinary skill in the art.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

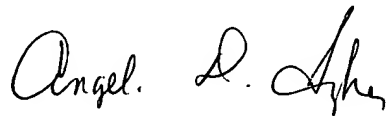
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph S. Machuga  
Examiner  
Art Unit 3762

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ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
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